# DEVICE FOR RADIAL OPTIC NEUROTOMY

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3 This application claims priority of Provisional Patent Application #60/397,793, filed 7/24/2002.

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## BACKGROUND OF THE INVENTION

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- The art of the present invention relates to eye surgical devices in general and more particularly 8 to an improved and modified form of a microvitreoretinal (MVR) blade having elements and features 9 especially suited for radial optic neurotomy (RON) as a treatment for central retinal vein occlusion 10(CRVO).
- Central retinal vein occlusion (CRVO) is a relatively common condition, reported to occur 12in approximately 60,000 new patients each year within the United States. Its etiology is poorly 13understood, with a wide array of medical and systemic disorders debated as to their potential 14causative effect. CRVO is most commonly reported in patients aged 50 to 80 years, with a statistical 15tendency towards those patients suffering from hypertension and/or glaucoma. The natural history 16of this condition can result in loss of vision due to extensive intraretinal hemorrhage, macular edema, 17iris neovascularization, neovascular glaucoma, and ischemic retinal infarct. Spontaneous resolution 18is uncommon; rather, it is most widely reported to have catastrophic consequences to affected 19patients.
- There is no effective curative therapy for CRVO. Panretinal photocoagulation can be 21effective in controlling neovascularization, while grid photocoagulation has been reported to be 22successful in resolving edema. However, neither therapy restores vision nor reverses the basic 23occlusive condition. Attempts to create a physiological shunt by way of a of high powered 24photocoagulating chorioretinal anastomosis has reported some success, but is similarly associated 25with a high rate of complications. Many theorize that the CRVO is associated with thrombus within 26the central retinal vein. As such, many developing therapies have concentrated on resolving the 27thrombus by means of cannulation of the central retinal vein and administration of "clot busting" 28agents (t-PA). While technically feasible, the clinical results and reproducibility of this procedure 29remain non-validated.
- An emerging hypothesis suggests that CRVO is a vascular complication secondary to a 31compartment syndrome. This condition is created as the optic nerve enters the eye, experiencing a

1 reduction in outer diameter from 3.0mm to 1.5mm at the optic nerve head. It is theorized that 2 congenital anatomical variances, connective tissue, persistent myelin sheaths, ocular motion, and other 3 factors may increase pressure within the scleral outlet compartment, thereby resulting in CRVO.

- A new surgical procedure, radial optic neurotomy, (RON) addresses this causative factor and, 5 in so doing, potentially provides a curative effect. By inserting a knife radial to the optic nerve head 6 and advancing a specified distance, the compartment syndrome may be relieved by relaxing the 7 cribiform plate, scleral ring, and adjacent sclera. Unfortunately, the greatest potential complication 8 of such a maneuver is hemorrhage. To address this complication, the present art device incorporates 9 design elements and features which minimize this threat.
- The present art device is best described as a radial optic neurotomy (RON) knife. The device 10 11comprises in its most basic form, a modified conventional microvitreoretinal (MVR) blade with a 12 single sharp nasal portion edge rather than the two opposing sharp edges, both nasally and medially 13as found in conventional MVR blades. Prior art conventional microvitreoretinal (MVR) knives or 14blades introduce a significant risk during the RON procedure as the sharp nasal and medial edges may 15 cause an inadvertent disruption or cutting of the central retinal vessels. The single sharp edge of the 16present art device allows for a radial incision of the optic nerve head, with the incision proceeding 17 nasally. In the present art device, the medial edge, i.e. the edge opposite the single sharp edge, of the 18 blade is specially dulled, thereby allowing atraumatic passage of the knife alongside the central retinal 19 artery and central retinal vein. The present art device further provides a depth gauge or measuring 20technique via the inclusion of a mark at a desired penetration depth distance from the device tip. 21Prior art conventional microvitreoretinal (MVR) knives or blades are unmarked, thereby leaving the 22 surgeon without indication as to the actual depth of penetration. This mark provides the surgeon with 23a specific reference as to the depth of the radial incision, thereby minimizing the potential for globe 24 perforation.
- Accordingly, it is an object of the present invention to provide a device for radial optic 26neurotomy having a sharp edge and a medial dulled edge which is capable of atraumatic passage 27alongside the central retinal artery and central retinal vein.
- Another object of the present invention is to provide a device for radial optic neurotomy 29having a depth gauge or measuring technique to optimize a desired penetration depth.

## SUMMARY OF THE INVENTION

- To accomplish the foregoing and other objects of this invention there is provided a device for 4 radial optic neurotomy. The apparatus is especially suited for use with and during the radial optic 5 neurotomy procedure.
- The present art device or RON blade first comprises a substantially asymmetrical "V" shaped tip having a distal point, the base or point of said "V" substantially representing the distal end of the 8 present device. In the preferred embodiment, the top or broad portion of said "V" shaped tip is 9 attached with a tip holding shaft having a proximally attached handle. Said asymmetrical "V" shaped 10tip comprises a first leg of said "V" having the single sharp edge and a second leg of said "V" 11 opposite said first leg comprising a burnished, dulled, or rounded edge.
- The preferred embodiment further places a laser mark onto both broad sides of said "V" 13shaped tip transitional taper area to function as a depth gauge. Again in the preferred embodiment, 14said laser mark is in the form of a line which is substantially perpendicular with the central shaft axis. 15Alternative embodiments may place one or more of said marks at any location which would indicate 16the proper depth of penetration during surgical use or place multiple marks to accommodate varying 17pathology and/or surgical nuances. Alternative embodiments may further utilize said mark as a partial 18line or other mark form which is scribed or marked in a fashion other than laser marking or which is 19positioned in a fashion which is not perpendicular with the central shaft axis or which is located onto 20only one side.
- As aforesaid, a handle or grip attaches with said central shaft opposite said "V" shaped tip and 22proximal to the user. Preferably said handle or grip is cylindrical in form, but may take many forms 23or shapes which allow a surgeon to easily utilize the device. The present art device is claimed as the 24tip in conjunction with the attached shaft and as a further embodiment, the tip with attached shaft and 25handle or grip.
- The "V" shaped tip of the present device may be manufactured from a plurality of materials, 27these include but are not limited to stainless steel, diamond, both natural and/or synthetic, ruby, 28obsidian, ceramic, or nickel-titanium alloys. In the preferred embodiment, the shaft is manufactured 29from stainless steel and the handle or grip is manufactured from a durable high temperature polymer

1 capable of withstanding autoclave temperatures. The shaft and handle may further be manufactured 2 from any material which is biologically safe for surgical use and further provides the lateral and 3 torsional strength required for surgical use. Further embodiments may also utilize an anti-reflective 4 surface treatment, coating, or process on the tip or shaft.

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## BRIEF DESCRIPTION OF THE DRAWINGS

- Numerous other objects, features and advantages of the invention should now become 8 apparent upon a reading of the following detailed description taken in conjunction with the 9 accompanying drawings, in which:
- Fig. 1 is a top plan view of a preferred embodiment of the device for radial optic neurotomy 11showing the substantially "V" shaped tip with laser mark and tip holding shaft.
- Fig. 2 is a left side plan view thereof, which is symmetrical with a right side plan view, of the 13device for radial optic neurotomy showing the substantially "V" shaped tip with laser mark and tip 14holding shaft.
- Fig. 3 is a cross sectional view thereof taken along line 3-3 in Figure 2.
- Fig. 4 is a rear side plan view thereof without attached handle or grip.
- Fig. 5 is a left side perspective view thereof of a preferred embodiment fully showing the 18substantially "V" shaped tip with laser mark, tip holding shaft, and handle or grip, all of which is 19substantially symmetric with a right side perspective view.
- Fig. 6 front side plan view thereof of a preferred embodiment showing the "V" shaped tip and 21tip holding shaft.
- Fig. 7 is a bottom side plan view thereof of a preferred embodiment showing the rounded edge 23 of the "V" shaped tip and tip holding shaft.

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## 25 DETAILED DESCRIPTION

Referring now to the drawings, there is shown in FIGS. 1 - 7 a preferred embodiment of a 27device for radial optic neurotomy 10 having a blade 12 with a sharp edge 22 on a first leg 20 and 28a dulled edge 28 on a second leg 26 and a depth gauge 30 placed distally from a point 16 of said 29blade 12. The device for radial optic neurotomy 10 is particularly adapted to relieve the aforesaid

1 compartment syndrome during the radial optic neurotomy, (RON) procedure with a minimal risk of 2 hemorrhage.

The present art device for radial optic neurotomy 10 first comprises a substantially 3 4 asymmetrical "V" shaped tip 14 having a distal point 16, the base or point 16 of said "V" 5 substantially representing the distal end of the present device. In the preferred embodiment, the top 6 or broad portion 18 of said "V" shaped tip is attached with a tip holding shaft 36 having a proximally 7 attached handle 38. Said asymmetrical "V" shaped tip comprises a first leg 20 of said "V" having 8 the single sharp edge 22 and a second leg 26 of said "V" opposite said first leg 20 comprising a 9 burnished, dulled, or rounded edge 28. In a preferred embodiment, said first leg 20 represented by 10said first single sharp edge 22 is angled approximately 12 degrees from the central axis 37 of said tip 11holding shaft 36. Also in a preferred embodiment, said second leg 26 represented by said dulled or 12rounded edge 28 is angled approximately 10 degrees from the central axis 37 of said tip holding shaft 1336, said angle rotationally opposite said first leg 20. Alternative embodiments may vary the 14aforementioned angles considerably without departing from the scope and spirit of the present In the preferred embodiment, the second leg 26 deviates from said 10 degrees as it 15 invention. 16approaches the base or point 16 of said "V"(i.e. distal end), thereby forming an angle of 17approximately 30 degrees relative to the central shaft axis 37. This deviation further places said 18second leg 26 or dulled edge 28 slightly across the central shaft axis 37 and toward the first leg 20 1 9 or sharpened edge 22, thereby shifting the distal point 16 across the central shaft axis 37 toward said 20 first leg 20 or sharp edge 22. The aforementioned deviation further ensures that the device 10 and 21the distal point 16 shall only cut on one side, i.e. the first leg 20 or sharp edge 22, when inserted near 22said optic nerve head. The aforesaid 30 degree deviation may be varied considerably without 23departing from the scope of the present invention provided that the aforementioned benefits are 24maintained. Alternative embodiments may provide said dulled second leg edge 28 without shifting 25said second leg 26 across the central shaft axis 37.

In the preferred embodiment, the sharpened edge 22 is formed from a substantially linear taper 27 plane 24 positioned from a line substantially parallel with said central axis 37 toward the first leg 20 28 of said "V" 14. Alternative embodiments may provide said first leg 20 sharpened edge 22 without 29 the aforesaid taper 24, provided said first leg 20 sharpened edge maintains the aforesaid cutting

1 characteristics.

- In the preferred embodiment, the tip holding shaft 36 is slightly smaller in diameter or width 3 than the top or broad portion of said "V" shaped tip 14. This configuration requires that the tip 4 attachment with said tip holding shaft 36 transitionally taper 40 to the shaft 36 dimensions. In the 5 preferred embodiment, this transitional taper 40 does not contain a sharpened edge. Alternative 6 embodiments may eliminate said transitional taper 40 or place a sharpened edge on the first leg 20 7 side of said transitional taper 40. The second leg 26 side of said transitional taper 40 further 8 maintains the dulled or rounded edge 28 to avoid cutting action on the second leg 26 side.
- The preferred embodiment further places a laser mark 34 onto both broad 18 sides of said "V" 10shaped tip 14 transitional taper 40 area to function as a depth gauge 30. Again in the preferred 11embodiment, said laser mark 34 is in the form of a line 32 which is substantially perpendicular with 12the central shaft axis 37. Alternative embodiments may place on or more of said marks 34 at any 13location which would indicate the proper depth of penetration during surgical use or place multiple 14marks to accommodate varying pathology and/or surgical nuances. Alternative embodiments may 15further utilize said mark 34 as a partial line or other mark form which is scribed or marked in a fashion 16other than laser marking or which is positioned in a fashion which is not perpendicular with the 17central shaft axis or which is located onto only one side.
- In one form of the preferred embodiment, the first leg **20** or sharpened edge **22** is 19approximately .090 inches, the laser mark **34** is positioned proximally from the distal point 20approximately .108 inches or 2.7 millimeters, the broad portion **18** of said "V" shaped tip **14** is 21approximately .0465 inches wide at its widest portion, the tip holding shaft **36** is approximately .033 22inches in diameter, and the distal point **16** is shifted across the central shaft axis **37** toward said first 23leg **20** or sharp edge **22** by .003 inches. The aforesaid dimensions are given for enablement purposes 24only and do not singularly represent the preferred embodiment. Alternative embodiments may vary 25the aforesaid dimensions considerably provided the first leg **20** sharpened edge **22** and second leg **26** 26dulled edge **28** characteristics are maintained.
- As aforesaid, a handle or grip 38 attaches with said central shaft 36 opposite said "V" shaped 28tip 14 and proximal to the user. Preferably said handle or grip 38 is cylindrical in form, but may take 29many forms or shapes which allow a surgeon to easily utilize the device. The present art device is

1 claimed as the tip14 in conjunction with the attached shaft 36 and as a further embodiment, the tip
2 14 with attached shaft 36 and handle or grip 38.

- During utilization of the radial optic neurotomy device 10, the surgeon inserts the 4 asymmetrical "V" shaped tip 14 radial to the optic nerve head and advances said tip 14 a specified 5 distance thereby relieving the compartment syndrome and relaxing the cribiform plate, scleral ring, 6 and adjacent sclera. In order to minimize hemorrhage and other complications, the first leg 20 sharp 7 edge 22 is positioned whereby a radial incision proceeds nasally to or away from the optic nerve head 8 and the second leg 26 dulled edge 28 proceeds alongside or near the optic nerve head, central retinal 9 artery, or central retinal vein without incision promotion, thereby allowing atraumatic passage of the 10 device 10.
- Those skilled in the art will appreciate that a radial optic neurotomy (RON) knife utilized for 12surgical decompression of central retinal vein occlusion (CRVO) has been shown and described. That 13said present art is capable of providing a radial incision on the nasal aspect of the optic nerve head, 14a relaxing incision to the scleral ring and cribiform plate by means of an extremely sharp edge on the 15nasal portion of the device. The device further provides an atraumatic passage of the knife past the 16central retinal vessels due to a burnished and dulled or rounded medial edge. The present art may 17further be utilized in general retinovascular ophthalmic surgery.
- Having described the invention in detail, those skilled in the art will appreciate that 19modifications may be made of the invention without departing from its spirit. Therefore, it is not 20intended that the scope of the invention be limited to the specific embodiments illustrated and 21described. Rather it is intended that the scope of this invention be determined by the appended claims 22and their equivalents.